

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

Applicant: MUKHOPADHYAY, Debasish )  
Serial No.: 09/243,237 )  
Confirmation # 2221 )  
Filed: 02/02/1999 )  
Title: HIGH PURITY WATER PRODUCED )  
BY REVERSE OSMOSIS )  
Art Unit: 1723 )  
Examiner: Fortuna, A. )

Assistant Commissioner for Patents  
Washington, D.C. 20231

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**RESPONSE UNDER C.F.R. SECTION 1.111**

Assistant Commissioner for Patents  
The United States Patent and Trademark Office  
Washington, D.C. 20231

Sir:

**RESPONSE**

This communication is responsive to the Second Official Action on the merits in this matter, mailed July 14, 2000. In view of the remarks and arguments made herein, the applicant respectfully requests reconsideration and further examination of this application.

In response to the various objections and rejections set forth in the Second Official Action, specific responses and remarks are set forth below. Accordingly, the applicant respectfully requests that the examiner reconsider the application, as amended.

**1. Rejection under 35 U.S.C. Section 103 (a)  
Based on Collentro, et al  
(U.S. Patents 5,766,479 and 5,670,053)**

First, the examiner has rejected claims 11-15, 25-27, 29 and 33 as being unpatentable over the Collentro et al. US Patents '479 and '053 as referenced above. However, the examiner's analysis is flawed. Specifically, the examiner indicates that the '479 patent has a product which has "TOC as bicarbonate in the range of 1 to 25 ppm". This is an incorrect statement of fact, since "bicarbonate" is an inorganic carbon component, and although it is included in a "TIC" analysis, it is not properly includable in a TOC analysis. For reference by the examiner, this is briefly discussed in the '053 patent itself, at col. 3, lines 38-44, in connection with a discussion of prior art US Patent 5,413,763, which claims a method and apparatus for measurement of TOC. Similarly, the examiner incorrectly utilizes a similar argument in connection with the '053 patent as "carbon dioxide" removal (TIC removal) is discussed at col. 8, lines 26-31, and not TOC as alleged by

the examiner (on page 2 of the office action, 4<sup>th</sup> line from the bottom of the page). With respect to the cited reference to TOC at col. 9, lines 24-40, no light is shed on the percentage removal, or percentage rejection, (as set forth and claimed in the instant invention) as only a final purity objective is stated. Further, with respect to col. 10, lines 34-37 as cited by the examiner on page 2, 3<sup>rd</sup> line from the bottom, the claim 5 noted is not persuasive of obviousness as it only speaks to carbon dioxide removal, not to TOC removal.

With respect to the examiner's arguments with respect to the step of removal in the second reverse osmosis membrane, as set forth on the last 2 lines of page 2 of the office action, referencing col. 9; lines 1-17 of the '053 patent, note that the cited section of the '053 patent speaks to removal of greater than 90 percent of highly soluble, always ionized species such as sodium, potassium, and chloride, rather than the "sparingly ionized" species as set forth in paragraph (d) of claim 11 of the instant invention. As silica is a "sparingly ionized" species, rather than an "always ionized" species at neutral pH, removal of silica to the degree claimed is not made obvious by either of the cited Collentro references.

With respect to claims 29 and 33, the argument advanced by the examiner is not persuasive. At last check, in the

new USP specifications for water, the old "oxidizable substances" test is replaced by a TOC test. The limit for both PW (Purified Water) and WFI (water for injection) for TOC is proposed to be 500 ppb. However, the *USP 23* monograph does not address limits for microbiological concentrations. Instead, an "action limit" is listed for microbiological contamination in Purified Water at 100 colony-forming units per milliliter. For new USP standards for WFI, an action limit of 10 cfu/100 mL is expected, while the old standard *USP XXII* does not include an action limit for the microbial limits in WFI. There, the endotoxin specification is expected to stay as it presently exists. Consequently, neither item, as cited by the examiner's reference to col. 9, lines 24-39 of the '053 patent, is persuasive, much less makes obvious, the claimed product of "virus free" and "bacteria free" water. This is particularly true in light of the specified cfu limits referred to, indirectly, by Collentro et al.

In summary, for the reasons cited, neither of the Collentro et al references teaches or suggests the invention claimed herein in claims 11-15, 25-27, 29, and 33. Consequently, it is respectfully requested that this basis of rejection be withdrawn.

**2. Rejection under 35 U.S.C. Section 103 (a)  
Based on Bhave, et al (U.S. Patent 5,645,727)**

Next, the examiner has rejected claims 11-36 as being obvious over Bhave, et al '727. Although Bhave teaches some "ultra pure water characteristics" in Table III, and provides a "trace metal analysis" in Table II, unfortunately, it is not persuasive with respect to the present invention, as claimed, since no analysis is provided of the starting feedwater. Consequently, it is not possible, from Bhave, to discern whether or not the claimed removal ratios are achieved in his invention. Moreover, while he does teach the production of ultrapure water, he does not teach the high efficiency removal of TOC and boron as taught herein. It is impossible to show, from Bhave itself, that Bhave's process achieves the claimed removal efficiency; moreover, it does not make obvious the claimed invention. Thus, it is respectfully requested that this basis of rejection be withdrawn.

**3. Rejection under 35 U.S.C. Section 103 (a)  
Based on Abe, et al (U.S. Patent 5,573,662)**

Next, the examiner has rejected claims 11-15 as being obvious over Abe et al., U.S. Patent No. 5,573,662. Simply stated, the examiner alleges that because Abe shows, in Table 7, the production of water with a TOC of 11 ppb, (after UV +MB 1<sup>st</sup> stage), and a TOC of 0.6 to 0.8 ppb (after

UV + MB 2st stage), then claims 11-15 are made obvious. However, a close examination of claims 14-15 show the production of a water stream with less than 0.4% of Total Organic Carbon in the feedwater, and with less than 0.34% of Total Organic Carbon in the feedwater, respectively. These removal efficiencies are not taught by Abe et al. More importantly, with respect to claims 11, 12, and 13, Abe requires two "post treatment" processes to achieve the removal efficiency that is claimed from feed water in the present invention. This only serves to point out the true value of water produced by the instant invention, specifically, that it can be made cheaper, as post treatment operations can be eliminated. Nothing in Abe teaches or makes obvious the provision of an ultrapure water product at such low cost.

For the reasons set forth above, it is believed that nothing in Abe et al teaches or makes obvious the low cost high purity water product as set forth and claimed herein. Therefore, it is respectfully requested that this basis of rejection be withdrawn.

**4. Obviousness (35 U.S.C. Section 103 (a))  
Based on Tao, et al (U.S. Patent 5,250,185)**

Finally, the examiner has rejected claim 16 as being unpatentable over Tao, et al '185. While Tao et al did not teach, suggest, or exploit his process for ultrapure water

production (he was instead concerned with decontamination of oil-field produced water before discharge to receiving waters), the examiner has correctly noted that at Table 1, removal of TOC from 171 mg/L in feedwater to 1.5 mg/L in permeate is taught. That amounts to a 98.8 % removal, or a 99.19% rejection. That is still not nearly as good of a rejection or removal as taught by the instant invention, but, does reach the value set forth in claim 16. However, the last time that the Federal Circuit visited this particular type of question in product-by-process claims, it was specifically decided that product by process claims serve as limitations in determining infringement, and thus a claim to a product is not infringed by the same product made by a different process. See Atlantic Thermoplastics Co., Inc. et al v. Faytex Corporation, 970 F.2d 834, 23 U.S.P.Q.2d 1481 (CAFC 1992); rehearing denied, 974 F.2d 1299, 24 U.S.P.Q. 2d 1138 (CAFC 1992). Here, process limitations set forth in claims 11 and 12 distinguish the claimed invention from the Tao process. Here, where the economic value of the product water lies primarily in its low cost of production (although for certain waters it also has the attribute of higher purity than effectively produced by other processes), the Patent Office should permit the applicant to define his product in terms of the production method of his business which provides the much sought after

economic benefit, i.e., the distinguishing technical process of production, as claimed. Importantly, it is now widely recognized that in claim analysis for infringement purposes, infringement requires the presence of every claim limitation. Moreover, a recently decided Federal Circuit case has determined that mere amendment of a claim will foreclose the benefit to the applicant of the once widely utilized Doctrine of Equivalents, in any attempt to obtain enforcement of a claim based on an equivalent of a claim limitation, if the amendment was made for any reason related to patentability. Thus, it is undeniably clear that claim limitations are strictly enforced by the courts, and that every claim limitation has relevance in defining the invention.

The applicant should not be foreclosed from action against the entity which takes economic benefit of his invention by the purchase of low cost, high purity water, simply by virtue of the long used excuse of the Patent Office that it "can't tell the difference" of a product produced by the claimed process from a similar product produced by a different process. Basically, that boils down to a proof problem, which is easily resolved in infringement litigation - which is the concern of the courts, not of the Patent Office.

For the foregoing reasons, it is respectfully requested that the rejection of claim 16 of this application, as presently set forth herein, be withdrawn.

**SUMMARY**

The applicant has invented a novel, economically important treated water composition, which in individual cases can be uniquely identified by reference to the feedwater from which the water composition is produced. However, as noted in the previous response, the inventor is faced with a rather common but difficult problem, namely, how can the novel and unobvious product of his process be adequately described? Given the infinite variety and complexity of available feedwaters from which to produce a treated water composition having trace amounts of solutes remaining therein, to describe such a product by an analytical analysis of the final composition, for a variety of starting feedwaters, would be a Herculean and virtually impossible task. On the other hand, the inventor and the undersigned patent practitioner face the claims construction problem created by the Federal Circuit's decision in Exxon Chemical Patents, Inc., et al v. Lubrizol Corporation, 77 F.3d 450, 1996 U.S. App. Lexis 3150, 37 U.S.P.Q.2d (BNA) 1767, (CAFC 1996), where merely describing in a claim the ingredients in a composition, which ingredients later react

in that composition, was deemed insufficient to validly protect the product as claimed. As the heart of the novel and unobvious product water composition results from treatment by a novel and unobvious process, as suggested in the above referenced Exxon Chemical Patents v. Lubrizol matter, the inventor has set forth his invention in terms of product-by-process claims.

It is respectfully submitted that in view of the arguments made above, the applicant's invention is not made obvious by the prior art of record, as the invention is now claimed. Therefore, reconsideration and withdrawal of all objections based on 35 U.S.C. §103 are respectfully requested

For the reasons discussed in detail above, it is believed that this application is now limited to claims which are clearly patentable over references of record.

Favorable consideration of this application is therefore believed to be in order and such action is earnestly solicited.

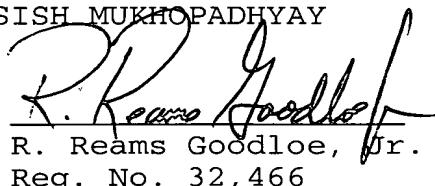
Finally, if any outstanding issues remain after review of this response, the applicant and the undersigned respectfully request that an interview at the Patent Office be scheduled to review the matter.

Done at Kent, County of King, State of Washington, on  
the 16th day of January, 2001.

Respectfully submitted,

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